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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/784,665

02/15/2001

Yiqun Wang

1001.1412101

2225

28075 7590 05/24/2010
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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/784,665	Applicant(s) WANG ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,24-28 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,24-28,30 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is in response to the amendment filed February 22, 2010.
2. Claims 22, 24-28, and 30-36 are currently pending, with claims 31-34 and 36 withdrawn from consideration.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 22, 24-28, 30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (US 4,610,665, hereinafter "Matsumoto") in view of Picha et al. (US 5,080,654, hereinafter "Picha") and Py (US 6,604,561).

Matsumoto discloses the invention substantially as claimed including a catheter (70), comprising: an elongate catheter shaft (71) having a proximal end, a distal end, a guidewire lumen (72) defined therethrough, and an inflation lumen (75) defined therethrough; a balloon (74) disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen; a port (76) disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen, and a self-sealing seal member (16) attached to the end of the port and covering the opening (Fig. 16 and 17). The seal (16) is pierceable, is generally planar, and may extend laterally beyond the flanged end of the port (Fig 11). A cap (78) is coupled to the port and disposed over the seal (Fig 17).

However, Matsumoto fails to disclose the seal member is releasably attached to the flanged end. Picha discloses a self-sealing seal member (20) that is releasably attached the flanged end of a port, and the flange helps to secure the elastomeric seal in place (col. 3, ln. 6-

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42). The seal is pierceable (col. 3, ln. 12 and 56-58), is generally planar at the proximal end (Fig 4), and may extend laterally beyond the flanged end (15) of the port (Fig 4). A cap (30) is coupled to the port and disposed over the seal (Fig. 5). It would have been obvious to one of ordinary skill in the art to modify the seal assembly of Matsumoto such that the seal member was releasably attached to the flanged end, since it is a well known feature as taught by Picha and it would provide the same function of maintaining a fluid-tight seal during insertion of and after removal of an injection member. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Furthermore, Matsumoto discloses the seal member comprises slits (17/18) that form a fluid tight seal about the piercing member (77), wherein the slits have a minimal width and the seal (16) is formed of an elastomeric material such that upon removal of the piercing member (77) the slits form a perfect seal to prevent inflation fluid from flowing out of the balloon.

However, Matsumoto teaches the slits (17/18) are pre-formed and thus fails to disclose the seal member has a solid cross-section. Py discloses a similar seal (226) disposed in a port (214). The seal (226) has a solid cross-section (Figs 2 and 13c) and is pierceable to deliver fluid therethrough (Figs 3 and 13a). Upon withdrawal of the piercing member (e.g. 140 or 282), a slit is formed (294) along the path of the piercing member (Fig 13b). The elastomeric material is sufficiently resilient to close upon itself and maintain a sealed condition despite the slit that was formed. However, a heating member may be used to fuse the elastomeric material and seal the slit such that the seal member has a solid cross-section to further ensure the seal forms a gas-tight seal after introduction of a piercing member (col 2, ll 10-22; col 5, ll 16-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was

made to modify the combination of Matsumoto and Picha such that the seal comprised a solid cross-section to further ensure fluid cannot pass through the seal unintentionally.

Response to Arguments

5. Applicant's arguments, see amendment, filed February 22, 2010, with respect to the rejection(s) of claim(s) 22, 24-28, 30, and 35 under Matsumoto and Picha have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Py (US 6,604,561).

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
May 19, 2010

/K. M. D./
Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734